

Application No.: 10/002,521  
Amendment and Response dated December 9, 2004  
Reply to Office Action of September 9, 2004  
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### REMARKS

Claims 1-3 and 21-24 remain in this application. Applicants respectfully request reconsideration in view of the following remarks.

#### Applicants' Response to 35 U.S.C. §102 Rejection over Pinchuk

Claims 1, 3 and 21-24 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 4,657,544 to Pinchuk (hereinafter "Pinchuk"). Applicants respectfully traverse the rejection on the basis that Pinchuk fails to disclose each and every element of Applicants' claims.

With respect to claims 1 and 3, the Examiner contends that Pinchuk discloses:

**a medical device/vascular graft comprising an implantable tubular extrudate comprising an interpenetrating polymer network comprising a non-expanded PTFE matrix having no node and fibril structure . . . the matrix having distributed therein discrete domains of an extractable polymeric material (salt crystals, although not polymeric, they are eventually extracted, and are not present in the end product), wherein upon exposure to sufficient dissolving medium or degradation temperature, the extractable polymeric material (salt) is extracted from the matrix to create pores (16) in the tubular extrudate . . . .**

(Office Action dated 9/9/04, at 2-3) (citations omitted). Therefore, the Examiner alleges that Pinchuk teaches an interpenetrating polymer network including non-expanded PTFE. The Examiner also alleges that Pinchuk teaches extraction of salt from the matrix to create pores, and thus, Pinchuk's end-product is the same as recited in Applicants' claims.

With respect to claim 21, the Examiner further contends that Pinchuk discloses an extractable polymeric material to comprise silicone. According to the Examiner, the silicone is claimed to be extracted. The Examiner alleges that the salt crystals that are extracted in Pinchuk create the same porous end-product as recited in Applicants' claim 21.

As regards claim 22, the Examiner further alleges that Pinchuk discloses the extractable polymeric material, i.e., salt crystals, being particulate and having a particle size of about 5-100 microns.

With respect to claim 23, the Examiner alleges that Pinchuk discloses an implantable, non-expanded, porous PTFE extrudate comprising non-expanded PTFE having no node and fibril structure and a plurality of pores distributed throughout. The Examiner further contends that Pinchuk teaches that the pores have a shape defined by an extracted polymeric material, and the polymeric material is in the form of a gel, liquid or flowable material. According to the Examiner, the salt crystals of Pinchuk "may have the shape of liquid or gel droplets or clumps."

Regarding claim 24, the Examiner alleges that Pinchuk discloses an implantable PTFE extrudate comprising a non-expanded PTFE resin having no node and fibril structure and a particulate polymeric component that is incompatible with the PTFE resin. The Examiner asserts that the salt crystals of Pinchuk correspond to the claimed extractable polymeric component because the polymeric component is not present in the end-product. Therefore, according to the Examiner, the salt crystals in Pinchuk create the same end-product as recited in claim 24.

Applicants' claims 1, 3, 21 and 22 all require a tubular extrudate that comprises an interpenetrating polymer network ("IPN"). Nowhere in Pinchuk is an IPN of PTFE and another polymer component disclosed, taught or suggested.

Applicants' claims 1, 3 and 21 were previously rejected over Pinchuk on the same grounds in the Office Action dated October 8, 2003. In response, Applicants submitted arguments over Pinchuk, particularly that Pinchuk fails to disclose an IPN, which the Examiner accepted. At that time, Applicants added claim 22, which also requires an IPN of PTFE and another polymeric component. This rejection over Pinchuk was not maintained in the subsequent Office Action, which was dated May 17, 2004. Therefore, based on the arguments submitted, Applicants understand the rejection to be overcome for claims 1, 3 and 21, and thus claim 22 as well.

More specifically, as discussed in Applicants' Amendment dated January 5, 2004, Pinchuk is directed to a cardiovascular graft formed from a two component biocompatible polymer system. The two component polymer system contains a polymer resin, which is polyurethane, silicone or PTFE, and a curing agent. Contrary to the Examiner's allegations, however, nowhere in Pinchuk is it disclosed, taught or suggested to form an IPN of PTFE and another polymer.

As previously described, an IPN is commonly understood in the art to mean a polymer containing two or more polymer networks, which are at least partially interlaced but not covalently bonded to each other. *See IUPAC COMPENDIUM OF CHEMICAL TERMINOLOGY* (2<sup>nd</sup> ed. 1997), exhibit attached. More specifically, an IPN is a combination of two polymers in which at least one is synthesized and/or crosslinked in the immediate presence of the other to form an interlaced network. *See U.S. Patent No. 4,764,560 to Mitchell; Col. 1, lines 63-66.* Accordingly, a mixture of two or more separate and independently pre-formed polymer networks is not an IPN. *See IUPAC COMPENDIUM OF CHEMICAL TERMINOLOGY.*

Pinchuk does not even suggest a mixture of PTFE and polyurethane or silicone as separate polymer networks, let alone an interlacing network of the polymers. Therefore, Pinchuk does not provide nor even suggest an IPN, as described above. Because Applicants'

compositions require an IPN, Pinchuk fails to anticipate this element of Applicants' claims 1, 3, 21 and 22.

With respect to claim 23, contrary to the Examiner's allegations, Pinchuk fails to teach or suggest an extractable polymer component in the form of a gel, liquid or flowable material. Pinchuk only discloses extraction of salt crystals from a polymer system. Salt is commonly understood to be "a colorless or white crystalline solid." THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE (4<sup>th</sup> ed. 2000) (emphasis added). Crystals are commonly understood to be "a homogenous solid formed by repeating, three-dimensional pattern of atoms, ions, or molecules." *Id.* (emphasis added). Therefore, one of ordinary skill in the art would understand the salt crystals of Pinchuk to be in the form of a solid. A solid form is a different chemical state from a gel, liquid or flowable form. Therefore, the salt crystals in Pinchuk are not a gel, liquid or flowable material.

Moreover, a gel is commonly understood to be "a colloid in which the disperse phase has combined with the dispersion medium to produce a semisolid material, such as a jelly." *Id.* A gel, therefore, is a dispersion of a substance in another medium. Nowhere in Pinchuk is a dispersion of salt crystals in any other material even suggested.

Although Pinchuk discloses the use of water to leach the salt crystals out of the polymer system, this does not anticipate the claimed liquid or flowable form. In particular, once Pinchuk's polymer tube is formed, it is leached in water, thereby dissolving the salt crystals. Nowhere in Pinchuk, however, is it disclosed or suggested to dissolve the salt crystals in water prior to adding them into the polymer system. Such a solution would defeat the purpose of Pinchuk. The salt could not be leached out of the polymer system to form pores if the salt crystals were already in solution with water. Accordingly, Pinchuk fails to teach or suggest the addition of salt to the polymer system in a liquid or flowable form.

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In view of the above, Pinchuk fails to disclose, teach or suggest an extractable component in a gel, liquid or flowable form. Contrary to the Examiner's allegations, the salt crystals of Pinchuk do not have the shape of "liquid or gel droplets or clumps." The only "clumps" possible in Pinchuk would be clumps of salt crystals, which as described above, are solid. Further, as taught by Pinchuk, the size and shape of its pores are determined by the salt crystals. *See* Pinchuk, at col. 4, lines 28-31. Therefore, Pinchuk does not teach or suggest pores that are defined by a gel, liquid or flowable material. As such, Pinchuk fails to disclose each and every element of Applicants' claim 23. Moreover, the Examiner agreed that this recitation overcomes Pinchuk as a reference, as stated in the Examiner's Interview Summary dated August 8, 2004.

Regarding Applicants' claim 24, the claim is directed to an intermediate product requiring a non-expanded PTFE resin and a particulate polymeric component which is incompatible with the PTFE resin. The claimed product, therefore, requires a particulate polymeric component that is incompatible with PTFE. Nowhere in Pinchuk is such a particulate polymeric component disclosed, taught or suggested. Salt crystals are not polymeric. Therefore, Pinchuk fails to anticipate each and every element of Applicants' claim 24.

In view of the above remarks, Applicants respectfully request reconsideration and withdrawal of the Section 102 rejection over Pinchuk.

**Applicants' Response to 35 U.S.C. §103 Rejection over Pinchuk in view of Dereume**

Claim 2 is rejected under 35 U.S.C. §103(a) as allegedly being obvious over Pinchuk in view of U.S. Patent No. 5,639,278 to Dereume et al. (hereinafter "Dereume"). Applicants respectfully traverse the rejection.

In addressing Pinchuk as a Section 102 reference, Applicants have already described in detail that Pinchuk does not provide nor even suggest a tubular extrudate having an IPN including PTFE and an extractable polymeric component. For the sake of brevity, Applicants

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will not repeat the discussion on Pinchuk.

For the same reasons that Pinchuk fails as a reference under 35 U.S.C. §102, the combination of Pinchuk and Dereume fail as a proper combination under 35 U.S.C. §103. Dereume is cited only for its teachings of combining a stent and a graft together and fails to teach or suggest anything of any relevance to the present invention as recited in the claims. Dereume clearly fails to cure the deficiencies of Pinchuk. The combination of Pinchuk and Dereume therefore fails to disclose each and every element of the claimed invention.

Withdrawal and reconsideration of this Section 103 rejection is therefore respectfully requested.

**Applicants' Response to 35 U.S.C. §103 Rejection over Zilla**

Claims 1, 3 and 21-24 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over U.S. Patent No. 6,540,780 to Zilla et al. (hereinafter "Zilla"). Applicants respectfully traverse the rejection.

The Examiner asserts that Zilla discloses an implantable medical device comprising a polymeric tubular extrudate having distributed therein discrete domains of an extractable polymeric material. According to the Examiner, the polymeric material of Zilla is extracted to create pores.

The Examiner, however, fails to assert that Zilla discloses or suggests an IPN of PTFE and an extractable polymeric material, which is required in claims 1, 3, 21 and 22. The Examiner fails to provide any evidence that Zilla suggests an IPN. Indeed, nowhere in Zilla is an IPN disclosed, taught or suggested. Thus, absent any assertion that Zilla discloses or suggests an IPN, and absent any evidence in the Zilla reference of such a disclosure or suggestion, the rejection fails to state a case of prima facie obviousness.

In particular, Zilla discloses graft material that requires thermoplastic elastomers, preferably polyurethanes. Helical channels are formed in the graft by including extractable fibers in the graft material. Zilla also discloses that the graft material may contain additional, non-extractable fibers for reinforcement, such as PTFE. Nowhere in Zilla, however, is it disclosed, taught, or suggested that any of these components, particularly polyurethane and PTFE, form an IPN. Zilla does not provide nor even suggest that these two polymers are interpenetrating in any manner. Rather, Zilla discloses a combination of preformed, non-extractable PTFE fibers and polyurethane graft material. Addition of PTFE fibers occurs, for example, by winding the PTFE fibers onto a mandrel with the graft material, or including PTFE fibers along with polyurethane fibers for reinforcement of a graft extrudate. The polyurethane fibers and the PTFE fibers are separate, preformed fibers, not an IPN. Therefore, Zilla's disclosure is merely a combination of two separate polymer fibers, and therefore, not an IPN as described above.

Furthermore, the Examiner previously rejected Applicants' claims over Zilla in the Office Action dated October 8, 2003. In response, Applicants submitted arguments over Zilla, which resembled those above, in the Amendment dated January 5, 2004. The Examiner failed to maintain this rejection in the subsequent Office Action. Applicants accordingly understand the rejection to be overcome. It is unclear why the Examiner is again reciting a rejection that was previously overcome. No explanation or clarification is provided, particularly in view of the fact that the majority of the Examiner's rejections are simply restated versions of those previously made and not new grounds of rejection.

Therefore, Zilla fails to disclose, teach, or suggest an IPN including PTFE and another extractable polymeric component. Furthermore, the Examiner has failed to assert that Zilla suggests such an IPN. As such, Zilla fails to suggest each and every element of Applicants' claims 1, 3, 21 and 22, and withdrawal and reconsideration of this rejection is respectfully requested.

With respect to Applicants' claim 23, the Examiner alleges that "particles, liquids and gels all are disclosed by Zilla as extractable materials." Zilla discloses extractable fibers and fillers, however, neither of these is in the form of a gel, liquid or flowable material.

More specifically, a fiber is understood to be "a slender, elongated, threadlike object or structure." THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE (4<sup>th</sup> ed. 2000). Fibers are "a fundamental form of solid." HAWLEY'S CONDENSED CHEMICAL DICTIONARY (13<sup>th</sup> ed. 1997). The fibers taught in Zilla, therefore, are solid, rather than in a gel, liquid or flowable state. As regards the fillers, Zilla describes them as "preferably spherical in shape," and provides desired diameters thereof. *See* Zilla, at col. 4, lines 57-60. Zilla discloses "protein beads" as suitable fillers. *Id.* at col. 4, line 63. One skilled in the art would understand such spherical structures, or beads, to be solids. Such structures cannot be considered a gel, liquid or flowable material. As such, Zilla fails to suggest each and every element of Applicants' claim 23.

As described in the discussion of Pinchuk above, Applicants' claim 24 is directed to an intermediate product. Claim 24 requires a PTFE resin and a particulate polymeric component that is incompatible with the PTFE resin. Zilla discloses spherical fillers, which may be extracted from the polyurethane material. Zilla, however, fails to disclose or suggest that its spherical filler materials are incompatible with PTFE. Thus, Zilla fails to suggest this element of Applicants' claim 24.

Therefore, Zilla fails to suggest each and every element of Applicants' claims 1, 3 and 21-24. Withdrawal and reconsideration of this Section 103 rejection is respectfully requested.

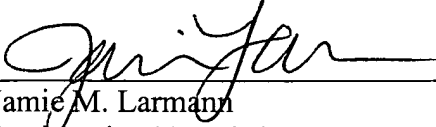
In view of the foregoing, Claims 1-3 and 21-24 are now believed to be in proper form for allowance. A favorable reconsideration of the application on the merits is earnestly solicited.



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If the Examiner has any questions regarding this Response, she is encouraged to contact the undersigned attorney.

Respectfully submitted,

  
Jamie M. Larman  
Registration No. 48,623  
Attorney for Applicants

HOFFMANN & BARON, LLP  
6900 Jericho Turnpike  
Syosset, NY 11791  
(973) 331-1700